K121937

JUL 2 6 2012

510(k) Summary

In accordance with 21CFR807.92, the following summary of information is provided;

Date	Jun 29th 2012
Submitter:	ALPINION MEDICAL SYSTEMS Co., Ltd. Address: 1, 6 and 7FL Verdi Tower, 72, Digital-ro(St) 26-gil(Rd), Guro-gu, Seoul, Republic of Korea 152-848,
Primary Contact Person	Donghwan Kim QARA Manager Address: 1, 6 and 7FL Verdi Tower, 72, Digital-ro(St) 26-gil(Rd), Guro-gu, Seoul, Republic of Korea 152-848, Phone: +82 70 7465 2068 Fax: +82 2 851 5594 Email: donghwan.kim@alpinion.com
Secondary Contact Person	Yuchi Chu Address: Suite 229, 10604 NE 38th Place, Kirkland, WA 98033, United States Phone: 425 949 4907 Fax: 425 949 4908 Email: ychu@alpinionus.com
Device Trade Name:	E-CUBE inno
Common/Usual Name:	Ultrasonic Pulsed Doppler Imaging System
Classification Names	System, Imaging, Pulsed Doppler Ultrasonic
Product Code:	Ultrasonic Pulsed Doppler Imaging System, 21CFR 892.1550 90-IYN Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO Diagnostic Ultrasound Transducer, 21CFR 892.1570, 90-ITX
Predicate Device(s)	K113690 LOGIQ i, LOGIQ e, Vivid e
Device Description:	E-CUBE inno product is a mobile ultrasound imaging system for medical diagnosis. This product can be used for the applications of abdominal, obstetrics, gynecology, small parts, cardiology, vascular, etc. The system platform provides optimal patient diagnosis workflow with ergonomic control panel with easy user interface, optimal image quality.
Indications For Use:	The device is intended for use by a qualified physician for the evaluation of soft tissue and blood flow in the clinical applications; Fetal; Abdominal (renal & GYN/pelvic); Pediatric; Small Organ (breast, testes, thyroid); Musculo-skeletal(Conventional); Musculo-skeletal (Superficial); Cardiac (adult); Peripheral Vascular (PV); and Urology (including prostate).

Technology: E-CUBE inno employs the same fundamental scientific technology as its predicate device.

Feature	Proposed E-CUBE inno ALPINION MEDICAL SYSTEMS Co., Ltd.	Predicate LOGIQ e GE Healthcare
510(k) Number	-	K113690
Indications for use	The device is intended for use by a qualified physician for the evaluation of soft tissue and blood flow in the clinical applications; Fetal; Abdominal, Pediatric; Small Organ (breast, testes, thyroid); Musculo-skeletal(Conventional); Musculo-skeletal (Superficial); Cardiac adult; Peripheral Vascular (PV); and Urology (including prostate).	The device is intended for use by a qualified physician for the evaluation of soft tissue and blood flow in the clinical applications; Fatal/OB; Abdominal(GYN & Urology); Pediatric; Small Organ (breast, testes, thyroid); Musculo-skeletal Conventional and Superficial; Cardiac (adult and pediatric); Peripheral Vascular (PV); Urology (including prostate); Intra-operative (abdominal, thoracic, PV) Neonatal Cephalic &Adult Cephalic; Trans-esophageal; Trans-rectal; Trans-vaginal (TV); and Thoracic/Pleural
	• Discussion of differences The individual functions of E-CUBE inno has essential performance and safety effectiveness same as LOGIQ e, even though E-CUBE inno has limited scope of the indications comparing with the predicate. Therefore, E-CUBE inno is substantially equivalent with predicate device.	
Dimensions and weight	Weight: approx. 7.2kg (excluding Option) Height: 83.5~415 mm Width: 410 mm Depth: 371 mm	Weight: approx. 4.6kg(with battery) Height: 61mm/1410 mm Width: 340mm Depth: 287mm/ 337mm with handle
Monitor	15 inch LCD Display size: 1024 X 768 Monitor tilt - More than 165 degrees	15 inch TFT LCD Display size : 1024 X 768 Monitor tilt - 160 degrees (maximum)
Electrical power	Voltage:24V 6.5A Frequency: 50/60Hz Power: 120 VA MAX with Peripherals	Voltage: 20V 5A Frequency: 50/60Hz Power: Max. 130 VA with Peripherals
Consol design	1 Active Probe Port Integrated HDD (Capacity: 500G) Rear Handle On-board Storage for Peripherals - B/W Printer, Color Printer, DVD RW USB ports, internal ECG	1 Active Probe Port Integrated HDD(Capacity: 160G) Rear Handle Lithium ion battery pack(Standard) On-board Storage for Peripherals - B/W Printer, Color Printer, DVD RW, USB ports, USB ECG(AHA/IEC) Support CWD Support

	● Discussion of differences E-CUBE inno has more storage capacity of image than Logiq e and it is not related with the safety and effectiveness and essential performance. E-CUBE inno doesn't include a Lithium ion battery pack but this is not essential parts.	
Operating Mode	B Mode M Mode Color Flow Mode Power Doppler Mode Pulse Wave Doppler Mode Continuous Wave Doppler SRI	B Mode M Mode Anatomical M mode Color Flow Mode Power Doppler Mode Pulse Wave Doppler Mode Continuous Wave Doppler Mode Tissue Doppler Imaging SRI
	● Discussion of difference E-CUBE inno includes essential operating mode for diagnosis and is Substantially Equivalent	
Labeling and/or promotional materials	Section 6 User manual Section 6A Catalog E-CUBE inno	Section 3B User manual GE Logiq e Section 3C Catalog GE Logiq e
Accessories or kits	Color printer B/W printer DVD-RW Ultrasonic gel Cidex OPA (disinfectant agents) Cidex Plus (disinfectant agents) SC1-6 Biopsy Starter kit L3-12 Biopsy Starter kit Patient ECG cable((AHA/IEC)	Color printer B/W printer DVD-RW Footswitch Lithium ion battery pack(Standard) Aquasonic 100 Scan Gel Scan Ultrasound Gel Cidex OPA (disinfectant agents) Sterile Ultrasound Probe Sheath Set Sterile Ultrasound Cord Sheath Set Sanitary Rectal/Vaginal Probe Cover Sterile Combination Probe and Cord Cover Set Sterile Ultrasound Probe Sheath Set for Wide Aperture Sector Probes USB ECG(AHA/IEC) Support Isolation/Docking Cart
	● Discussion of difference E-CUBE inno doesn't include a lithium ion battery, Footswitch but this is not essential parts.	

Measurement and Calculation functions	1. General 1) B-Mode 2) M-Mode 3) Doppler Mode	1. General 1) B-mode 2) M-Mode: 3) Doppler Mode
	2. Abdomen 1) B-Mode 2) M-Mode 3) Doppler Mode	2. Abdomen 1) B-Mode 2) M-Mode 3) Doppler Mode
	3. Small Parts 1) B-Mode 2) M-Mode 3) Doppler Mode	3. Small Parts 1) B-Mode 2) M-Mode 3) Doppler Mode
	4. Obstetrics 1) B-Mode 2) M-Mode: 3) Doppler Mode	4. Obstetric 1) B-Mode: 2) M-Mode: 3) Doppler Mode
	5. Gynecology 1) B-Mode 2) M-Mode: 3) Doppler Mode	5. Gynecology 1) B-Mode 2) M-Mode 3) Doppler Mode
	6. Cardiology 1) B-Mode 2) M-Mode 3) Doppler Mode	6. Cardiology 1) B-Mode 2) M-Mode 3) Doppler Mode:
	7. Vascular 1) B-Mode 2) M-Mode 3) Doppler Mode	7. Vascular 1) B-Mode 2) M-Mode 3) Doppler Mode
	8. Urology 1) B-Mode 2) M-Mode 3) Doppler Mode	8. Urology 1) B-Mode 2) M-Mode 3) Doppler Mode
	9. Pediatrics 1) B-Mode 2) M-Mode 3) Doppler Mode	9. Pediatrics 1) B-Mode 2) M-Mode 3) Doppler Mode
Acoustic output	Track 3	Track 3

<Conclusion>

The indications for use, material, form factor, performance, and safety characteristics between E-CUBE inno and the predicate device are the same except for Intra-operative (abdominal, thoracic, PV); Neonatal Cephalic &Adult Cephalic; Trans-esophageal; Trans-rectal; Trans-vaginal (TV); and Thoracic/Pleural. The primary difference is cosmetic structure and component used only. Therefore, we can claim the substantially equivalence of E-CUBE inno to the predicate device.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

E-CUBE inno has been evaluated for biocompatibility, acoustic output as well as thermal, electrical, electromagnetic, and mechanical safety, and has been found to conform to applicable medical device safety standards. E-CUBE inno and its application comply with voluntary standards as detailed in this premarket submission. The following quality management system measures were applied to the development of E-CUBE inno:

- NEMA UD2, UD3
- AIUM Medical Ultrasound Safety
- IEC60601-1
- IEC60601-1-2
- IEC60601-2-37
- ISO 10993-1

Transducer materials and other patient contact materials are biocompatible.

Summary of Clinical Tests:

The subject of this premarket submission, E-CUBE inno, did not require clinical studies to support substantial equivalence.

Conclusion: ALPINION MEDICAL SYSTEMS Co., Ltd. considers E-CUBE inno to be as safe, as effective, and performance is substantially equivalent to the predicate device.

ALPINION MEDICAL SYSTEMS Co., Ltd. will update and include in this summary any other information deemed reasonably necessary by the FDA or the requirements will be published in guidance documents.

Appendix B – Decision Summary for Web Posting

Decision Summary, K 121937

This 510(k) was reviewed under OIVD's Pilot Triage Program. This program represents an internal workload management tool intended to reduce internal FDA review resources for 510(k) applications that are of good quality upon receipt by FDA.

The information in the 510(k) is complete and supports a substantial equivalence (SE) determination. Please refer to the applicant's 510(k) summary for a summary of the information that supports this SE determination.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

JUL 26 2012

Mr. Donghwan Kim
QARA Manager
Alpinion Medical Systems Co., Ltd.
1, 6 and 7 FL, Verdi Tower
72, Digital-ro (St) 26-gil (Rd), Guro-gu
SEOUL 152-848
REPUBLIC OF KOREA

Re: K121937
Trade/Device Name: E-CUBE inno
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: June 28, 2012
Received: July 2, 2012

Dear Mr. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the E-CUBE inno, as described in your premarket notification:

Transducer Model Number

C1-6i	L3-8i
SP1-5i	L3-12i

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can

be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Jeffrey Ballyns at (301) 796-6105.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Indications for Use Statement

510(k) Number (if known):

Device Name: E-CUBE inno

Indications for Use:

The device is intended for use by a qualified physician for the evaluation of soft tissue and blood flow in the clinical applications; Fetal; Abdominal (renal & GYN/pelvic); Pediatric; Small Organ (breast, testes, thyroid); Musculo-skeletal(Conventional); Musculo-skeletal (Superficial); Cardiac (adult); Peripheral Vascular (PV) and Urology (including prostate).

Prescription Use ✓ AND/OR Over-The-Counter Use_____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In-Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K 5121937

Diagnostic Ultrasound Indications for Use

E-CUBE inno Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation								
	B	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)
Ophthalmic									
Fetal	N	N	N		N	N	N	N	
Abdominal	N	N	N	N	N	N	N	N	
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric	N	N	N	N	N	N	N	N	
Small Organ (breast, testes, thyroid)	N	N	N		N	N	N	N	
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (*Conventional*)	N	N	N		N	N	N	N	
Musculo-skeletal (*Superficial*)	N	N	N		N	N	N	N	
Intravascular									
Cardiac Adult	N	N	N	N	N	N	N	N	
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel	N	N	N		N	N	N	N	
Urology (including prostate)	N	N	N		N	N	N	N	

N = new indication; P = previously cleared by FDA; E = added under appendix

* Combined: B/M, B/PWD, B/CF, B/PD, B/CF/PWD, B/CF/M, Dual B; **Other: 3D, 4D

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Concurrence of CDRH, Office of In-Vitro Diagnostic Devices (OIVD)

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

510K K121937

Diagnostic Ultrasound Indications for Use

E-CUBE inno with C1-6i Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation								
	B	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)
Ophthalmic									
Fetal	N	N	N		N	N	N	N	
Abdominal	N	N	N		N	N	N	N	
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric	N	N	N		N	N	N	N	
Small Organ (breast, testes, thyroid)									
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (*Conventional*)									
Musculo-skeletal (*Superficial*)									
Intravascular									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel									
Urology (including prostate)	N	N	N		N	N	N	N	

N = new indication; P = previously cleared by FDA; E = added under appendix

* Combined: B/M, B/PWD, B/CF, B/PD, B/CF/PWD, B/CF/M, Dual B; **Other: 3D, 4D

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Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
K121937

Diagnostic Ultrasound Indications for Use

E-CUBE inno with SP1-5i Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation								
	B	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)
Ophthalmic									
Fetal									
Abdominal	N	N	N	N	N	N	N	N	
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric	N	N	N	N	N	N	N	N	
Small Organ (breast, testes, thyroid)									
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (*Conventional*)									
Musculo-skeletal (*Superficial*)									
Intravascular									
Cardiac Adult	N	N	N	N	N	N	N	N	
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel									
Urology (including prostate)									

N = new indication; P = previously cleared by FDA; E = added under appendix

* Combined: B/M, B/PWD, B/CF, B/PD, B/CF/PWD, B/CF/M, Dual B; **Other: 3D, 4D

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Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In-Vitro Diagnostic Device Evaluation and Safety

510K K121937

Diagnostic Ultrasound Indications for Use

E-CUBE inno with L3-8i Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation								
	B	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)
Ophthalmic									
Fetal									
Abdominal									
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric	N	N	N		N	N	N	N	
Small Organ (breast, testes, thyroid)	N	N	N		N	N	N	N	
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (*Conventional*)	N	N	N		N	N	N	N	
Musculo-skeletal (*Superficial*)	N	N	N		N	N	N	N	
Intravascular									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel	N	N	N		N	N	N	N	
Urology (including prostate)									

N = new indication; P = previously cleared by FDA; E = added under appendix

* Combined: B/M, B/PWD, B/CF, B/PD, B/CF/PWD, B/CF/M, Dual B; **Other: 3D, 4D

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Concurrence of CDRH, Office of In-Vitro Diagnostic Devices (OIVD)

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K121937

Diagnostic Ultrasound Indications for Use

E-CUBE inno with L3-12i Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation								
	B	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)
Ophthalmic									
Fetal									
Abdominal									
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric	N	N	N		N	N	N	N	
Small Organ (breast, testes, thyroid)	N	N	N		N	N	N	N	
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (***Conventional***)	N	N	N		N	N	N	N	
Musculo-skeletal (***Superficial***)	N	N	N		N	N	N	N	
Intravascular									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel	N	N	N		N	N	N	N	
Urology (including prostate)									

N = new indication; P = previously cleared by FDA; E = added under appendix

* Combined: B/M, B/PWD, B/CF, B/PD, B/CF/PWD, B/CF/M, Dual B; **Other: 3D, 4D

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